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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/423,545 | 11/12/1999 | KENJI SHIBATA | 2139.15 | 6874 |

5514 7590 09/09/2004

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EXAMINER

GUPTA, ANISH

ART UNIT PAPER NUMBER

1654

DATE MAILED: 09/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/423,545

Applicant(s)

SHIBATA ET AL.

Examiner

Anish Gupta

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 7-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 17 is/are rejected.
- 7) ☒ Claim(s) 15 and 16 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6-18-04 has been entered.

2. Applicant's election of the species of Compound 23, SEQ ID NO. 31 in Paper No. 12 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

A search was conducted for the elected species of SEQ ID. NO. 31 and then extended to SEQ. 5 in the previous office action. In light of the amendment, the sequence search was again extended to SEQ ID NO. 1-4, 6-7, 16-30 and 32. No prior art was found on the elected species and, in accordance with the MPEP, the search of the Markush - type claim was be extended. Prior art was found that anticipates or renders obvious the Markush - type claim. The Markush - type claim is rejected and claims to the non - elected species held withdrawn from further consideration. Thus, claims 7-14 are withdrawn from consideration as corresponding to a non elected species.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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3. Claims 1-6 and 17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Note that for the purposes of the 112 rejection, all claims even though they are withdrawn from consideration are included in this rejection. This is to further prosecution in the instant application.

Lack of Literal Support

The claims have been amended to recite, since the original filing of the claims in the amendment dated 12-2-03 and 6-18-04, that the “peptide does not comprise five or more glycine or lysine residues.” The MPEP states in section 2173.05(i):

“Any negative limitation or exclusionary proviso must have basis in the original disclosure. If alternative elements are positively recited in the specification, they may be explicitly excluded in the claims. See In re Johnson, 558 F.2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977) (“[the] specification, having described the whole, necessarily described the part remaining.”). See also Ex parte Grasselli, 231 USPQ 393 (Bd. App. 1983), aff’d mem., 738 F.2d 453 (Fed. Cir. 1984). The mere absence of a positive recitation is not basis for an exclusion. *Any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Note that a lack of literal basis in the specification for a negative limitation may not be sufficient to establish a prima facie case for lack of descriptive support.*

Here, the specification lacks any literal support for the amendment to specifically exclude “five or more glycine or lysine residues” in the peptide claims. Applicants have not provided locations where one can find the appropriate support for the new limitations. The MPEP states that it is a burden on the “Applicant should therefore specifically point out the support for any amendments

made to the disclosure.” See MPEP 2163.06. Applicants have not specifically pointed to the “support” for the claimed amendment.

It is acknowledged that a specification does need to provide literal support for a amendment. Support can be supported in the specification through express, implicit, or inherent disclosure (See MPEP 2163). However, the specification also lacks any inherent or implicit support in the specification. The specification does not provide any guidance that five lysine’s or glycine’s or any amino acids for that matter should be avoided. Reading the specification as a whole one cannot conclude that five consecutive amino acids should be avoided. To the contrary, the specification provides sufficient support that five amino acids is permissible since all of the Markush groups allow for five or more consecutive amino acids. Thus the specification also lacks inherent support.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-6 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Kemp et al.

The claims are drawn to cyclic peptides that have at least 7 amino acid residues.

The reference discloses the peptide Cycl(Gly-Cys-Gly-Gly-Cys-Gly-Gly-Cys-Gly) (see abstract). This peptide anticipates the claims since, in accordance with claim 1, the peptide is 9 amino acids in length, X1 is not present, X2 is gly, X3 is not present, X4 is cys, X5 is gly, X6 is not present, X7 is Gly, X8 is Cys, X9 is Gly, X10 is Gly, X11 is Cys X 12 is Gly. The rest of the X

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values are not present by virtue of n1 being 0. The cyclizatoin occurs through an amide bond, thereby meeting the limitation of claim 2.

5. Claims 15-16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Notice of Rejections

6. To further prosecution, the following 112 Second paragraph rejection have been made to give applicants notice that these claims contain 112 Second paragraph issues. In no way does the rejection imply that they have been included in a prior art search. Since the claims have been subject to election of species, only those claims that read on the elected species have been examined for prior art purposes.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 3-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recite that Xp (np=1) and Xq (nq=1) wherein Xp is 1 and Xq is X15 or X17, or X8.

Further the claims recite that the Xq is either at the C-terminal, is not at the C-terminal etc...

First, the claims recites the limitation "np=1" in 1. There is insufficient antecedent basis for this limitation in the claim in the base claim.

Secondly, it is unclear how these Xq's and Xp's relate the generic structure. Take claim 10 as an example. The claim recites, in the pertinent part, "wherein Xp (np=1) is an N-terminal residue and Xq (nq=1) is a X8." Does this imply that Xp is X1 or any X1 through X11 or are X1-X11 all Xp? In essence, it is unclear as to the position of Xq.

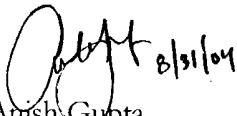
It seems that Applicants wish to denote Xp and Xq as a single amino acid within the broader formula (I). However, the base claim does not do an effective job in stating that only one Xp and Xq are present. If this is indeed what applicants desire to be the interpretation of the claim, then positions Xp and Xq are also unclear. Some claims recite that Xp and Xq are either N-terminal residues, C-terminal residues or are neither N-terminal or C-terminal residues. It is unclear which amino acids are desired to be the N-terminal residues and C-terminal residues since those claims making reference to the terminals do not recite a specific X value, i.e. X1, X2 et... These claims do not seem to limit the base claim. The base claim recites that $q > p$. Thus the N-terminal can only be any one of X1-X11 and the C-terminal can only be any one of X8-X17. A claim, such as claim 3, which recites that Xp is an N-terminal residue and Xq is a C-terminal residue does not further limit the claims since one of X1-X11 have to be a N-terminal residue to allow $q > p$. The presence of one of X1-X11 would also qualify it as an Xp variable.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (571)272-0965. If attempts to reach

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the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campbell, can normally be reached on (571) 272-0974. The fax phone number of this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Anish Gupta
Patent Examiner